NOV 17 2004

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Noah Bartsch Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8552 Fax: (574) 372-4605
Date:	10-04-2004
Trade Name:	*Wristore*™* Distal Radius Fracture Fixator
Common Name:	External Fixator
Classification Name:	Smooth or threaded metallic bone fixation fastener Single/multiple component metallic bone fixation appliances and accessories
Classification Reference:	21 CFR § 888.3040, 3030
Predicate Devices:	Millennium Medical Technologies, Inc., *Wristore* Fixator, K012294, cleared March 4, 2002 Immedica, Inc, *TransFx* Self-Drilling External Fixation Anchor Pin, K001228, cleared July 7, 2000
Device Description:	The *Wristore* Distal Radius Fracture Fixator is a single use external fixator designed to provide stable fracture fixation. The lightweight, radiolucent construct incorporates self-drilling bone pins and K-wires to provide secure fracture fixation and to capture fracture fragments.
Intended Use:	The *Wristore* Distal Radius Fracture Fixator is indicated for external fixation of the upper extremity.

*Trademark of Millennium Medical Technologies, Inc.

Comparison to Predicate Device:	The *Wristore* Distal Radius Fracture Fixator has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices.
Performance Data:	The results of non-clinical (laboratory) performance testing demonstrate that the device is safe and effective.

*Trademark of Millennium Medical Technologies, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

Mr. Noah Bartsch
Specialist, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581

Re: K042761
Trade/Device Name: Wristore™ Distal Radius Fracture Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: October 4, 2004
Received: October 5, 2004

Dear Mr. Bartsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

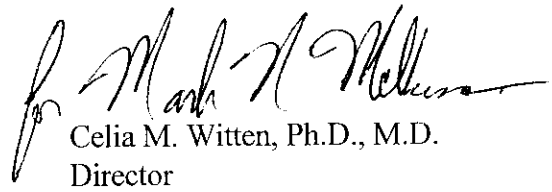
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Wristore™* Distal Radius Fracture Fixator

*Trademark of Millennium Medical Technologies, Inc.

Indications for Use:

The *Wristore*™* Distal Radius Fracture Fixator is indicated for external fixation of the upper extremity.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042761